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June 26, 1998

Food and Drug Administration Dockets Management Branch (HFA-305) 12420 Parklawn Drive Room 1-23Rockville, MD 20857

Re: Docket Number 97N-0451

Dear Sirs:

We are submitting these comments on behalf of the Chilean Exporters Association (CEA). The CEA is a trade association whose member companies ship approximately 85 percent of the total fresh fruits and vegetables exported from Chile to all world markets. Last season, Chile exported 170 million cases of fresh fruit and vegetables that generated FOB returns of \$1.4 billion.

Chile is a major supplier of fresh fruit and vegetables to the United States market during the North American winter. One of the most important functions performed by the CEA is the publication and distribution of a guideline to all companies involved in the export of Chilean fruit and vegetables that contains information on the sanitary and phytosanitary requirements of all 70 export markets for Chilean fruits and vegetables. The regulations of the USEPA and the FDA are contained in this guideline. In addition, the CEA has been a party to a bilateral agreement between the Government of Chile's Agriculture and Cattle Service and the USDA for the administration of quarantine protocols for the treatment of Chilean fruits and vegetables as a condition of entry to the US market.

The cooperative efforts of the CEA, FDA, EPA, USDA and the Government of Chile have been cited as a model for other countries to follow, when planning to establish markets for their food exports in the United States. All of the entities involved believe that these cooperative programs have been highly successful in assuring the American consumer of a safe, sanitary and wholesome supply of fresh fruit during a time of the year when such a supply is not available from Northern Hemisphere sources.

Given the substantial importance of our products to the

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continuous year around availability of fresh produce, we are following closely the development of President Clinton's Food Safety Initiative and the voluntary guidelines being proposed in this proceeding. For this reason, we have the following comments:

- 1. The CEA endorses the view that assuring the safety of the food supply is the shared responsibility of everyone involved from the farm to the table. We agree with the U.S. agencies involved that it is useful and helpful to publish voluntary guidelines that will help to avoid contamination of fresh fruits and vegetable exports to the United States. The CEA will assist in this effort through its role in distributing the guidelines and assisting in their adoption and implementation.
- 2. In general, the voluntary guidelines proposed are consistent with good agricultural practices that are generally accepted and implemented in Chile. Accordingly, we endorse the recommendations contained in the proposed guidelines.
- 3. We are concerned, however, that the implementation of mandatory regulations may be transformed into non-tariff trade barriers that could be used to limit access for our products to the U.S. markets. Such a non-tariff trade barrier might arise by the imposition of requirements applied to imports, and not to domestic sources of production, harvest, packing, shipping, storage or distribution.

The Food Safety Initiative was launched in a media and political climate focused on foreign sources of food products. In fact, the program was announced in connection with political maneuvering surrounding a Congressional vote on approval for fast track trade negotiating authority. Political activity and media attention to imported products since that time has continued to suggest, without a scientific basis, that imported foods are less safe than domestically produced product. The article "Food Safety and Fresh Fruits and Vegetables: Is There a Difference Between Imported and Domestically Produced Product?" (copy enclosed) clearly demonstrates the absence of any factual statistical basis for discriminating between imported and domestic fruits and vegetables on phytosanitary grounds.

- 4. We recommend that the future efforts of the U.S. regulatory agencies proceed through internationally recognized mechanisms, such as the Codex Alimentarius, to assure consistency with international trade law and to avoid the imposition of unilateral restrictions that could be transformed into nontariff trade barriers.
- 5. Further, we recommend that the U.S. agencies keep in perspective the importance of fresh fruit and vegetables to a well-balanced and healthy diet. In the United States, politics and media reporting of political events tend to focus exclusively on risks without appropriate attention to benefits. Further, the political and media discussions tend to amplify risks without the perspective of whether the risks are remote, widespread or even offset by much

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greater benefits. We believe that the U.S. regulatory agencies have a continuing obligation to communicate accurate information on food safety issues in order to counter media and political distortions.

6. Finally, we pledge our continued cooperation in all efforts to improve and assure the health and safety of Chilean fruit and vegetable exports to the U.S. and other world markets.

Respectfully submitted

David A. Holzworth

United States General Counsel Chilean Exporters Association





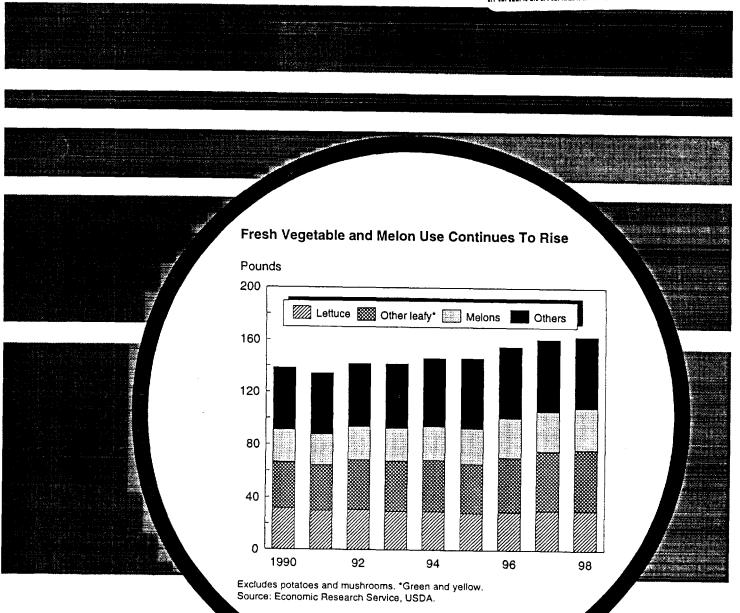
Economic Research Service

VGS-274 April 1998

Vegetables and Specialties

Situation and Outlook Report

SUBVGS403998-001



Food Safety and Fresh Fruits and Vegetables: Is There a Difference Between Imported and Domestically Produced Products?

Glenn Zepp, Fred Kuchler, and Gary Lucier¹

Abstract: Consumers and food handlers indicate that health risks due to bacterial contamination and pesticide residues rank high among their food concerns. However, scientists and regulatory personnel generally view contamination by microbial bacteria and naturally occurring toxins as greater dangers to human health than pesticide residues. Compared with animal products, in relatively few instances, fresh produce is identified as the vehicle carrying disease-causing pathogens. Yet, evidence suggests that fresh fruit and vegetables are becoming the conveyance for microbial pathogens more frequently than in the past. Foodborne illness outbreaks in the United States have been linked with both imported and domestically grown produce. There is no clear evidence that health risks due to pesticide residues or microbial bacterial contamination are greater with either imported or domestically grown produce.

Keywords: Food safety, foodborne illness, fruits and vegetables, imports, HACCP, pesticide residues.

Human nutrition research increasingly indicates that a well-balanced diet, rich in fruits and vegetables, promotes good health and may reduce the incidence of certain diseases. The Five-A-Day For Better Health campaign, jointly sponsored by the National Cancer Institute and the Produce for Better Health Foundation, representing the fruit and vegetable industry, urges Americans to consume at least five servings a day of fruits and vegetables. U.S. dietary guidelines go even further, suggesting five to nine servings a day as most beneficial (U.S. Department of Agriculture and U.S. Department of Health and Human Services). Fruits and vegetables provide vitamins, minerals, and the fiber essential to a balanced diet.

Americans appear to be responding to this "eat more fruits and vegetables" message. Annual per capita consumption during the 1990's averaged 84 pounds (13 percent) more than during the 1980's. The gains have occurred among both fresh and processed items. Consumption has increased for fresh products such as grapes, bell peppers, carrots, and onions, as well as for processed items such as frozen sweet corn, broccoli and canned tomato products. The biggest gains, however, have occurred among fresh produce items.

Despite the benefits derived from eating fruits and vegetables, consumers and others express concern about their lic attention on the safety of foreign-grown products.

In October 1997, President Clinton proposed legislation to permit Food and Drug Administration (FDA) inspection of foreign food-safety practices and to halt imports of fruits and vegetables from countries that do not meet U.S. standards. The Federal Government, with input from the domestic and international agricultural community, intends to issue guidance on sound agricultural and manufacturing practices

food's safety due to pesticide residues and microbial

pathogens in the food system. Such doubts are sometimes

amplified due to uncertainty on the part of scientists about

cides. In addition, an increasing—though still small—num-

ber of reported foodborne disease outbreaks are being traced

Prevention (CDC) have identified fresh produce as the vehicle carrying a variety of pathogens linked with foodborne

illness outbreaks in recent years (table A-1). Several of these

outbreaks involved imported produce and have focused pub-

the long-term health risks from low-level intake of pesti-

to fresh produce. The Centers for Disease Control and

The purpose of this article is to provide perspective on the relative importance of the various causes of foodborne risks as they relate to fruits and vegetables and to examine the available statistics for evidence of differences in food risks between imported and domestically produced product.

for fruits and vegetables within 1 year.

Economic Research Service/USDA

¹Zepp (retired) and Lucier are agricultural economists with MTED and Kuchler, agricultural economists with FRED, Economic Research Service, USDA.

Table A-1--Foodborne disease outbreaks traced to fresh produce, 1990-96

Year		Vehicle	Cases	States	Source 1/
	Pathogen		(No.)	(No.)	
1990	S. Chester	Cantaloupe	245	30	C.A.
1990	S. Javiana	Tomatoes	174	4	U.S.
1990	Hepatitis A	Strawberries	18	2	U.S.
1991	S. Poona	Cantaloupe	>400	23	U.S./C.A.
1993	E. coli O157;H7	Apple cider	23	1	U.S.
1993	S. Montevideo	Tomatoes	84	3	U.S.
1994	Shigella flexneri	Scallions	72	2	C.A.
1995	S. Stanley	Alfalfa sprouts	242	17	N.K.
1995	S. Hartford	Orange juice	63	21	U.S.
1995	E. coli O157:H7	Leaf lettuce	70	1	U.S.
1996	E. coli O157:H7	Leaf lettuce	49	2	U.S.
1996	Cyclospora	Raspberries	978	20	C.A.
1996	E. coli O157:H7	Apple juice	71	3	U.S.

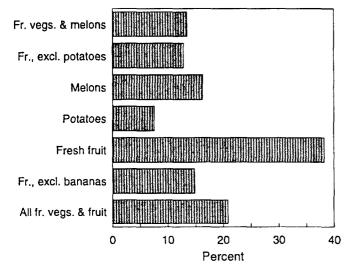
1/ C.A. =Central America, U.S. = United States, N.K. = not known.

Source: Tauxe, 1997.

Imports Rising

Both the quantity of U.S. fresh fruit and vegetable imports and their share of domestic consumption are rising. Imports made up 21 percent of U.S. fresh produce consumption in 1996, up from 17 percent in 1990 (figure A-1). A substantial part of this increase was apples and summer stone fruits, such as peaches, plums, apricots, and nectarines from Southern Hemisphere countries. Newly harvested apples, for example, arrive from Chile and New Zealand during the spring and early summer and compete with U.S. apples held in storage. Also, Chile supplies summer fruits to the United States during the winter and early spring, when cold weather precludes growing these commodities domestically.

Figure A-1
Imports as a Percent of Fresh Produce
Consumption, 1996



Source: Economic Research Service, USDA.

The United States is also importing more of its fresh vegetables, primarily from Mexico, Canada, and Central American countries. Mexico has long been a major supplier of winterfresh vegetables such as tomatoes, peppers, cucumbers, squash, eggplant, and green beans. However, during the 1980's and 1990's, Mexico and several Central and South American countries expanded their U.S. trade in frozen products such as broccoli, cauliflower, and snow peas and fresh products such as raspberries and asparagus.

Total imports accounted for 16.4 percent of all (fresh and processed) fruit and vegetable consumption in 1996, but there are substantial differences among products (table A-2). Iceberg lettuce imports, for example, account for less than 1 percent of consumption, whereas virtually all of the bananas consumed in the United States are imported.

Table A-2--U.S. fresh fruit and vegetable consumption and

import shares	, selected products, 1996		
		Import share of	
ltem	Domestic	domestic	
	consumption	consumption	
	Lb/person	Percent	
All fruits & vegetables	766	16.4	
All fresh produce 1/	310	20.9	
Potatoes	50	7.6	
Bananas	28	99.5	
Iceberg lettuce	23	0.5	
Apples	20	5.0	
Onions	18	13.0	
Tomatoes	18	34.0	
Watermelon	17	10.0	

1/ Total for selected commercially produced fresh fruit and vegetables.

Source: Economic Research Service, USDA.

Imports as a Percent of Fresh Vegetable Use



Source: Economic Research Service, USDA.

Risk Highest from Microbes And Natural Toxins

Scientists and regulatory personnel generally view contamination by microbial bacteria and naturally occurring toxins as the greatest foodborne dangers to human health. Epidemiologic data from the Centers for Disease Control and Prevention (CDC) indicate that microbial pathogens caused 79 percent of the 2,423 reported foodborne disease outbreaks and 90 percent of the 77,373 cases of associated illness in the United States between 1988 and 1992 (Bean et.al.). CDC defines a foodborne-disease outbreak as the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. The outbreaks reported by CDC, however, represent only a small fraction of the total number of foodborne illnesses each year. The Council for Agriculture and Science Technology estimates that microbial pathogens in food cause between 6.5 and 33 million cases of human illnesses in the United States and up to 9,000 deaths annually (CAST, 1994).

The CDC data indicate that fruits and vegetables were the vehicle of transmission for 64 (6 percent) of the 1,072 outbreaks for which a specific food was identified (table A-3). Five percent of the illnesses from these outbreaks were linked with fruits and vegetables, as were 22 percent of the

deaths. In over half of the reported outbreaks, however, the food carrying the pathogen remains unknown.

Not all of the outbreaks linked with fruits and vegetables. however, are tied to fresh produce. More than a third of the outbreaks were botulism poisoning caused by Clostridium botulinum. Although the spores of C. botulinum are commonly found in soil, botulism poisoning is usually associated with consuming improperly canned vegetables. Botulism poisoning involves a highly potent toxin that can cause death if not treated immediately and properly.

In addition, the CDC recorded six outbreaks associated with consuming mushrooms. All but one of these was due to consuming poisonous wild mushrooms. Several types of wild mushrooms produce highly poisonous natural toxins that cause illness or death when they are confused with edible species and eaten.

Despite the relative infrequency of fresh produce being identified as the vehicle for foodborne disease, there is evidence that fruits and vegetables are becoming a more frequent carrier. One reason may be that several foodborne infectious agents have been either newly described or newly associated with fruit and vegetable transmission in the last 20 years (Tauxe, 1997). E. coli O157:H7, for example, first identified as a pathogen in 1982 and originally linked with hamburger, showed that it could survive in low acid products when unpasteurized apple juice was identified as the vehicle for an outbreak in 1993. And, Cyclospora, known previously only as a cyanobacterialike organism, received its current classification in 1992, and emerged as a foodborne pathogen in outbreaks traced to imported Guatemalan raspberries in 1996.

Imported vs. Domestically Grown

The available data are not detailed enough to identify differences in the safety of imported and domestically produced products. CDC investigations of foodborne outbreaks have identified both imported and domestically grown produce as vehicles for microbial pathogens. The Guatemalan raspberry incident was highly publicized and raised consumer awareness of the potential for imported produce to bear foodborne pathogens. An outbreak of Hepatitis-A in 1997, linked with

Table A-3--Reported foodborne disease outbreaks, cases of illness, and deaths, 1988-92 1/

	All confirmed vehicles			Fruit/vegetable vehicle		
Year	Outbreaks	Cases	Deaths	Outbreaks	Cases	Deaths
1988	206	11,160	16	14	374	3
1989	237	8,882	5	21	1,072	0
1990	242	11,688	11	15	602	5
1991	236	10,427	5	12	308	1
1992	151	6,318	4	2	92	Ó
1988-92	1,072	48,475	41	64	2,448	9

1/ Excludes cases with no known vehicle of transmission.

Source: Complied from reports by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

strawberries grown in Mexico and frozen in the United States, further spotlighted imported produce. At the same time, outbreaks of foodborne diseases were linked with domestically grown products. A 1997 E. coli O157:H7 outbreak involving unpasteurized apple juice in several Western States and an outbreak involving cider in the Northeast are two examples. Other foodborne outbreaks have involved cantaloupe, watermelons, tomatoes, fresh basil, alfalfa sprouts, and lettuce.

The fact that the point of contamination can not always be determined complicates comparing the safety of imported and domestically produced products. In the case involving frozen strawberries, for example, the raw produce was grown in Mexico, but the berries were processed in a plant in the United States. It has not been determined whether contamination occurred before the berries entered the United States or whether it occurred during processing in this country.

Contamination of fresh produce can occur anywhere in the production and marketing chain, including during production-oriented processes like irrigating (polluted water, manure), harvesting and packing (workers with unsanitary hands due to lack of proper sanitation), and washing (polluted water). However, foodborne illnesses are most frequently attributable to food handling and preparation practices, the most common being improper holding temperatures (Bean et.al.). Poor personal hygiene of food handlers, inadequate cooking, and contaminated equipment also are frequently implicated with foodborne illnesses. The CDC reports several outbreaks of illnesses associated with fresh fruits and vegetables cross-contaminated when they were sliced on unsanitized surfaces following meat and poultry.

Monitoring for Microbial Contaminants

The Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services' Public Health Service, is responsible for ensuring the safety and wholesomeness of all foods sold in interstate commerce except for meat, poultry, and eggs, which are under USDA jurisdiction. FDA conducts research on contamination detection and prevention practices and sets standards for enforcing federal regulations and guidelines on food sanitation and safety. It also monitors the safety of the food system by inspecting manufacturing plants and feed mills producing medicated or nutritionally-supplemented animal feeds that are part of the human food chain.

The FDA uses a combination of plant inspections and information dissemination to minimize foodborne pathogens. Traditionally, the food industry and its regulators have depended on spot-checks of manufacturing conditions and random sampling of final products to ensure the safety of domestically produced food. This system is now being augmented by a relatively new strategy known as Hazard

Analysis Critical Control Points, or HACCP, which emphasizes prevention of food safety hazards. HACCP involves identifying critical points in a food production process where potential hazards can be controlled or eliminated. Then measurable standards that insure safe food are developed for these critical points and the processes monitored to insure that the standards are met. Each of these steps has to be based on sound scientific and technical knowledge, such as published microbiological studies.

Although the use of HACCP procedures in the fresh produce industry is voluntary, a number of producers, packers, and processors follow HACCP-like practices. One reason is that the produce industry has a considerable financial incentive to avoid microbial contamination of their products. Foodborne outbreaks can result in widespread adverse publicity for the industry producing the commodity identified as the vehicle. Such publicity raises consumer concerns about the safety of the commodity and results in reduced sales. Publicity surrounding the outbreaks of Cyclospora in 1996 and Hepatitis-A in the spring of 1997 reportedly diminished consumer demand for raspberries and strawberries, respectively, in those seasons.

FDA also has the responsibility for insuring the safety of imported fruits and vegetables. By law, imported products must meet the same standards as domestic goods. The bulk of FDA-regulated imports are cleared for immediate distribution based on the Agency's review of the shipment's records. If a problem is suspected, inspectors then physically examine or take a sample for laboratory analysis. However, only a small portion of imported produce is actually sampled as it enters the country.

Pesticide Concerns Appear Excessive

Pesticide residues in the food chain and their effects on human health are a controversial and complicated subject and have received considerable debate in the past 30 years. Surveys routinely show that consumers are very concerned that pesticide residues in foods will compromise their health. In a nationally representative USDA survey of meal planners and preparers, 22 percent of the respondents indicated that pesticide residues were their greatest health concern (Unnevehr, et al., 1995). Forty-three percent identified bacterial contamination as their major concern.

Risk perception studies indicate that concerns about pesticide dietary risks may be out of proportion with the actual danger. For distant future events, individuals have difficulty evaluating risks and often overstate them. For example, in a study of attitudes towards (low probability) risks associated with the use of household chemicals, Viscusi and Magat (1987) found that consumers overestimated the actual dangers. This finding was consistent with an earlier study by Lichtenstein and others (1978), which found that individuals overestimate risks associated with a wide class of low-probability fatality events.

Risks from pesticides include cancers, and risk assessors typically measure probabilities of cancer from pesticide dietary intake in cases per million population (National Research Council, 1987). Compared with most other tabulated causes of death and illness, cancer from pesticide dietary intake is clearly a low-probability risk and, if the findings of risk perception studies apply widely, are likely to be overestimated by consumers.

That many consumers express concern with pesticide residues in their food is not surprising because of the extensive news coverage the topic receives. During 1969-1995, the three major television networks showed 493 evening news stories on pesticides, devoting 873 minutes to the topic. This was more than to any other foodborne hazard (tabulated from the Vanderbilt Television News Archive). Pesticide news stories appeared every year during this time, while there were relatively few news stories about microbial contamination until 1985 (an outbreak of Salmonella was reported and since 1993 E. coli contamination of hamburger was reported).

Ambiguity over the nature of pesticide risks in news stories may also help to confuse consumer perception of the hazards. More than half of the television news coverages did not identify who or what was at risk (consumers, farm workers, environmental quality, or other). However, the continuous flow of information has served to frequently remind consumers that there may be reasons for concern with pesticides.

Are Imported Fruits and Vegetables More Risky Than Domestic?

The available data on pesticide residues do not provide a clear answer to the question of whether there are differences in the safety of imported and domestically grown produce. FDA's regulatory monitoring program has typically shown that imported produce violates tolerance limits more frequently than domestically grown produce (FDA, 1993). However, this greater frequency of violations in itself does not reveal whether there is a difference in the level of health risk. To answer health risk questions, one needs to know the amount of specific pesticides ingested and the toxicity of each (Chaisson et.al., 1991). To distinguish health risks of domestic and imported produce, the critical question is the level of exposure to each chemical from each source.

Both FDA and USDA have pesticide sampling programs that provide information for a limited number of commodities about the amount of specific pesticides in imported and domestic produce (Roy, et al., 1995, and USDA, AMS, 1997). Results from these programs indicate that some pesticide residues were detected only in domestic produce; some were found only in imported products; and some were found in both, sometimes at clearly different levels. Because different chemicals have different health effects, there is no obvious way to compare the safety of imported and domestic products when they contain different types of pesticides.

Even when the same pesticides are found on imported and domestic products, differences in health risks are not much clearer. Studies of pesticide residues in imported and domestic grapes and peaches, for example, do not reveal whether imports are riskier than domestic food because the domestic fruit contained higher levels of some residues while the imported product contained higher levels for others (Kuchler et al., 1996). Scientists have not reached a consensus on how to sum the total effects when more than one type of chemical is present in the food.

Frequently, the pesticides detected in fresh fruits are ones added after harvest in order to retard rot during storage and transportation. Virtually all of the residues found on bananas, for example, and 88-90 percent of residues on citrus were the result of post harvest treatments (Kuchler, et al., 1996). If packinghouse operators have incentive to treat domestically produced fruit destined for domestic markets, there likely is a greater incentive to treat when fruit is grown outside the United States, as such produce must survive a longer transportation period. To a large extent, it is the use of post-harvest fungicides that make importing fruit economically feasible.

Some scientists ignore differences between domestic and imported food, arguing that conventionally produced foods pose virtually zero risks from pesticides (Ames and Gold, 1996). Thus, they argue that any concerns with pesticides in foods are misplaced—that concerns with toxicity are unfounded because the results of toxicity experiments on rodents fed large doses of pesticides cannot be extrapolated to low human dietary intake. On the other hand, scientific evidence about low dose pesticide potency (ability to generate adverse health outcome) cannot yet prove a chemical is safe. Whether the intake of pesticide mixtures amplifies carcinogenic potency or whether pesticides function as endocrine disrupters is not likely to be well understood for many years. As scientists cannot prove chemicals to be safe, some critics may argue that pesticides are hazardous. They can use the existence of uncertainty to argue that food does not meet reasonable levels of safety (see, for example, Center for Science in the Public Interest, 1997).

Conclusion

Scientists and regulatory personnel generally view contamination by microbial bacteria and naturally occurring toxins as the greatest foodborne dangers to human health. However, there is no clear evidence of differences in the safety of imported and domestically produced products. Both imported and domestically grown produce have been linked with outbreaks of foodborne illnesses. Compared

with animal products, fresh produce is identified as the vehicle carrying disease-causing pathogens in relatively few instances. Yet, evidence suggests that fresh fruits and vegetables are becoming the conveyance for microbial pathogens more frequently than in the past.

Risk studies indicate that consumer concern about pesticide dietary risks may well be out of proportion with the actual danger. Compared with most other tabulated causes of death and illness, cancer from pesticide dietary intake appears to be a low-probability risk.

Although FDA's regulatory monitoring program has typically shown that imported produce violates pesticide residue tolerance limits more frequently than domestically grown produce, the data do not answer the question of whether there are differences in health risks for imported and domestically grown produce.

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